The Impact of Audio/Video In-study Interview Monitoring Implementation on Subject Recruitment

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ABSTRACT

INTRODUCTION: In the perspective of diminishing drug-placebo differences in current clinical trials in schizophrenia sponsors are implementing various monitoring methodologies including audio/video recordings of individual subject interviews to increase the scrutiny of individual ratings. Research sites are often reluctant to utilize these methodologies mainly because of the fear that having such a methodology in place could affect recruitment. We present a pooled analysis of recruitment at individual research sites in eight separate international clinical trials to address the question whether by implementing audio/video monitoring methodology the recruitment at the sites is affected.

METHODS: For the current analysis data was pooled from 8 separate schizophrenia trials. Sites are requested to record each screening/randomization PANSS subject interview using a proprietary audio/video recording system and submit for evaluation to an independent reviewer. While the use of the system is not mandatory for the individual subjects, sites are strongly encouraged to utilize it for every subject screened and/or randomized depending on trial methodology. For the purposes of the analysis sites are considered compliant if they utilized the system for at least one subject screened and/or randomized. Sites that have not used the system for any of the subjects are considered non-compliant. Two tailed t-test analysis on all pooled data was performed to compare the number of subjects randomized at research sites by compliance.

RESULTS: The overall data pool consisted of 2340 randomized subjects. Sites compliant with the audio/video monitoring system randomized on average 5.81 subjects compared to non-compliant sites with an average randomization of 3.52 subjects (t=-6.41, df=508, p <0.001). Compliant sites randomized on average significantly more subjects even when we only analyzed sites with more than 5 subjects randomized.

CONCLUSIONS: The initial analysis indicates that implementing audio/video surveillance methods should not represent a major obstacle to the recruitment at individual sites. Sites compliant with the monitoring system randomized on average significantly more subjects than sites that were non-compliant and this observation was true even when we analyzed only sites with at least 5 subjects randomized. While overall in the available dataset there were more non-compliant sites than those compliant when we analyzed only sites with at least 5 subjects randomized the picture was reversed and there were more subjects randomized.

REFERENCES

Alpha, Larry; Benedetti, Fabrizio; Fleischhacker, W. Wolfgang, Kane, John M. (2012): Placebo-related effects in clinical trials in schizophrenia: what is driving this phenomenon and what can be done to minimize it? Int J Neuropsychopharmacol, pp. 1–12.